



February 10, 2023

Vascular Solutions, Inc.
c/o James Chapman
Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K070938

Trade/Device Name: Thrombi-Paste® Thrombin/gelatin powder paste hemostat
Regulatory Class: Unclassified
Product Code: QSX

Dear James Chapman:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 6, 2007. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSX.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vascular Solutions, Inc.
% Mr. James Chapman
Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, Minnesota 55369

AUG - 6 2007

Re: K070938

Trade/Device Name: Thrombi-Paste® Thrombin/gelatin powder paste hemostat
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 29, 2007
Received: July 2, 2007

Dear Mr. Chapman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. James Chapman

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long, sweeping horizontal line extending to the right.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K070938

Device Name: **Thrombi-Paste® Thrombin/gelatin powder paste hemostat**

Indications for Use:

The Thrombi-Paste® Thrombin/gelatin powder paste hemostat is applied topically for temporary control of moderate to severely bleeding wounds and for the local management of surface bleeding from vascular access sites and percutaneous tubes and catheters.

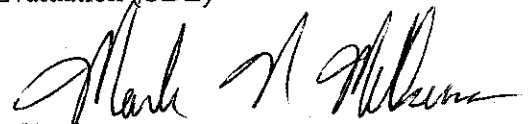
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K070938

510(k) Summary
(As required by 21 CFR 807.92(c))

AUG - 6 2007

510(k) Number: _____
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Date Prepared: April 2, 2007

Submitter Information

Submitter's Name: Vascular Solutions, Inc.
Address: 6464 Sycamore Court
Minneapolis, MN 55369

Establishment Registration 2134812

Contact Person: James Chapman
Regulatory Affairs Associate
Phone: (763) 656-4380
Fax: (763) 656-4253

Device Information

Trade Name: Thrombi-Paste® Thrombin/gelatin powder paste hemostat.
Common Name: Topical hemostat
Classification Name: Unclassified
Product Code: FRO
Regulation: Not Applicable

Predicate Device(s)

The predicate devices are the currently marketed D-Stat® Flowable hemostat (K012293) and ThrombiGel® Thrombin/gelatin foam hemostat (K063860).

Device Description

Each Thrombi-Paste® Thrombin/gelatin powder paste hemostat includes the following components;

A 10 mL syringe with attached mixing luer filled with 550mg of powdered absorbable gelatin sponge, USP (manufactured by Vascular Solutions, Inc. (VSI)),

A vial of Bovine-derived Thrombin (5,000 IU, supplied to VSI by King Pharmaceuticals, U.S. license # 977),

A diluent vial (5 mL, Supplied to VSI by Chesapeake Biological Laboratories, U.S. registration # 1123903),

Mixing accessories (10 mL syringe and needleless, non-coring vial access device) and
Applicator tips (1 - small bore tip, 1 - large bore tip).

The pouch containing the syringe with gelatin powder also contains a desiccant packet to maintain low moisture levels.

Intended Use/Indications for Use

The Thrombi-Paste® Thrombin/gelatin powder paste hemostat is applied topically for the temporary control of moderate to severely bleeding wounds or, the local management of surface bleeding from vascular access sites and percutaneous catheters or tubes.

Summary of Non-Clinical Testing

Testing included assessment of the physical properties of the Thrombi-Paste® Thrombin/gelatin powder paste hemostat and its ability to achieve its intended use. Bench testing of the physical properties of the Thrombi-Paste® Thrombin/gelatin powder paste hemostat confirmed the suitability of the device for its intended use. The following physical tests were performed;

pH Testing
Thrombin Activity Testing
Pot-life Testing
Delivery Force
Tip Kink Testing
Hemostatic Suspension Mass
Wetting / Mixing Time
Biocompatibility

K070938

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Vascular Solutions, Inc.
Thrombi-Paste® Thrombin/gelatin powder paste hemostat
510(k) Summary
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Summary of Clinical Testing

No human clinical testing was required for this device.

Statement of Equivalence

The Thrombi-Paste® Thrombin/gelatin powder paste hemostat is substantially equivalent to the currently marketed D-Stat® Flowable hemostat and ThrombiGel® Thrombin/gelatin foam hemostat based on a comparison of the indications for use and the technological characteristics of the device.

Conclusion

The Thrombi-Paste® Thrombin/gelatin powder paste hemostat is substantially equivalent to the currently marketed D-Stat® Flowable hemostat and ThrombiGel® Thrombin/gelatin foam hemostat based on the technological characteristics, and sterilization methods. Bench tests confirmed the suitability of the device for its intended use.